

REMARKS

Upon entry of this Amendment, claims 1-11 are all the claims pending in the application. Claims 5-11 have been added. Claim 2 is rejected under 35 U.S.C. §112, first and second paragraphs; claims 1-4 are rejected under 35 U.S.C. §102 as being anticipated by Bambot et al. (2003/0135122) and claims 1-4 are further rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang et al. (USP 6,834,122) in view of Bambot et al.

For the reasons set forth below, Applicant respectfully traverses the rejections and requests favorable disposition of the application.

Argument

35 U.S.C. § 112

In regard to the rejection of claim 2 under 35 U.S.C. § 112, first and second paragraphs, Applicant respectfully submits that the claims, as presently presented, satisfy each requirement thereof. In particular, “[t]he proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. “ MPEP §2181 at 2100-224, citing *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, (Fed. Cir. 1999). Further, “unless the means plus-function language is itself unclear, a claim limitation written in

means-plus-function language meets the definiteness requirement in 35 U.S.C. 112, second paragraph, so long as the specification meets the written description requirement in 35 U.S.C. 112, first paragraph." MPEP §2181 at 2100-224, citing *In re Noll*, 545 F.2d 141, 149, (CCPA 1976).

Regarding claim 2, Applicant submits that the means-plus-function language is clear and, further, a skilled artisan would understand from the specification what structure performs the recited functions. For example, at paragraph [0029] of the specification, it is disclosed:

In keeping with the invention, any one or more of the following system components, input processor 210, the classifier 250 and the image processor 270, may be realized in hardware or software. More particularly, any one or more of the system components may comprise a microchip, hardwired or programmed to perform functions described herein. Further, any one or more of the system components may comprise program code for causing a computing device, e.g. a processor or computer, to perform the functions described herein. The program code may be embodied in a computer readable medium such as a storage element or a carrier wave. Suitable storage elements include CD ROMs, floppy disks, smart tokens, etc. Although not explicitly disclosed given the functional description set forth herein, suitable program code instructions may be generated by the skilled artisan without undue experimentation.

Thus, as a skilled artisan would understand, in accordance with at least one exemplary embodiment, the various functions of the recited means of claim 2 are carried out by one or more **microchips** that are either hardwired, such as, for example, in an application specific integrated chip (ASIC) or discrete components; programmed

with specific software, such as with respect to a programmed microprocessor; or some combination of both. The skilled artisan would understand that the disclosed **microchips**, whether hardwired devices or a programmable **processor** or **computer**, are exemplary structures disclosed in the specification that correspond to the input processor 210, the classifier 250 and the image processor 270.

With respect to the **means for normalizing** recited in claim 2, it is disclosed, for example at paragraph [0033] that "input processor 210 preferably normalizes variations [in] peak magnitude by dividing each spectrum of the data cube by the area under the spectrum." Further, regarding the **means for extracting** pixel data, at paragraph [0036] it is disclosed that "image processor 210 extracts features of the spectra that are particularly useful in discriminating normal cervix tissue from diseased cervix tissue."

With respect to the **means for compressing**, at paragraph [0058] it is disclosed that "input processor 210 performs the steps of bin-averaging in both scale and time to produce a 16X16 representation that is then vertically raster-scanned to a vector with 256 coefficients." Regarding the **means for assigning**, the specification, at paragraph [0065], discloses that within classifier 250 "[a] region on the cervix may be annotated by assigning it a class label which corresponds to one of the following diagnoses..."

Lastly, regarding the **means for generating**, paragraph [0068] discloses "[i]mage processor 270 receives the output from classifier 250 and generates a two-dimensional image having regions that may be color-coded according to tissue classification."

Therefore, based on at least the various portions of the specification cited above, a skilled artisan would understand from reading the specification that the structure corresponding to each of the means recited in claim 2 is, for example, the microchip(s) disclosed at paragraph [0029] of the specification and discussed above. For at least this reason, claim 2 satisfies the requirements of 35 U.S.C. § 112, first and second paragraphs, and the rejection of claim 2 under these sections should be withdrawn.

35 U.S.C. § 102

With respect to the prior art rejection of claims 1-4 under 35 U.S.C. § 102(e), Applicant respectfully submits that Bambot et al. (US 20030135122) is directed to a method and device that is significantly different than Applicant's invention and, accordingly, fails to teach each and every limitation recited in the claims of the present application.

The Present Invention

The present invention is directed to a method and apparatus for generating a two dimensional image of a cervix from a three-dimensional hyperspectral data cube. (Abstract). As disclosed, fluorescence spectroscopy refers to a known collection of research which is a particularly effective tool for diagnosing cervical intraepithelial neoplasia (CIN). A particular known technique is known as hyperspectral diagnostic imaging (HSDI). Devices that employ HSDI techniques produce hyperspectral data cubes composed of multiple spatially aligned images of the cervix, each image corresponding to one of many spectral channels. (Par. [0006]).

Useful diagnostic information, however, is difficult to extract from the hyperspectral data cubes in their native format. To address this difficulty, the invention disclosed and claimed in the present application provides a method and attendant device that generates a two-dimensional histological map of the cervix from the three-dimensional hyperspectral data cube. According to one embodiment, the three-dimensional data cube is composed of 50 spatially aligned fluorescence images, each comprising approximately 172 X 172 pixels.

The spectrum of each pixel of each fluorescence image is then analyzed and the aggregate of the analyses is used to determine whether or what type of cancerous tissue is present. Peak magnitude of the spectral analysis, for example, is good discriminatory data when comparing different data points of an individual patient. Difficulty arises, however, when data from different patients is being compared. This is due, for example, to large statistical variations in peak magnitude data between patients.

To account for the large statistical differences, the present invention includes normalization of the individual fluorescence spectral signals. For example, in accordance with one embodiment, each spectrum of the data cube is divided by the area under the spectrum. Specifically, "each 50-channel spectrum is interpolated using a 128-point cubic spline function whereupon the area under the curve is estimated by integrating the spline function." (Par. [0033]). Each element of the originally generated

spectrum is divided by the calculated area and a normalized spectrum is, thus, obtained.

Rejection under 35 U.S.C. § 102

Bambot is directed to a method and device wherein “excitation electromagnetic radiation is used to illuminate a target tissue and electromagnetic radiation returned from the target tissue is analyzed to determine the characteristics of the target tissue.” (Par. [0016]). Bambot does not disclose normalizing fluorescence spectral signals collected from a hyperspectral data cube, as required by each of claims 1-4. Indeed, at paragraph [0178] Bambot discloses that “the invention could also be implemented using a multi-modal hyperspectral imaging (MHI) camera system.” Bambot does not, however, provide any disclosure whatsoever regarding how such a system would be used. Most significantly, Bambot does not provide any disclosure regarding how hyperspectral data would be normalized. In fact, Bambot does not even mention normalization of data in the context of hyperspectral imaging data.

Applicant recognizes that general normalization of data is mentioned in the various paragraphs identified in the grounds of rejection. For instance, at paragraph [0130] it is disclosed that “fluorescence and reflectance intensities are corrected for background light and *normalized* to the intensities measured off a calibration target.” It is further disclosed, at paragraph [0131] that a spectral discriminant factor must be corrected for blood absorbance, e.g., to account for artifacts in the spectral data related to local bleeding, “by *normalizing* the discriminant factor to blood reflectance.” There is

no disclosure, however, describing how either of these, or any other, normalization procedures is carried out. Further, there is no suggestion that either of these procedures would even be desirable in the event hyperspectral imaging camera briefly mentioned at the end of the specification were used.

It is well established that for a reference to anticipate a claim, the reference "must be enabling" with respect to the claimed features. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994)(citing *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987)). Here, the asserted reference to Bambot is not enabling with respect to the "normalization" processes disclosed. Even if the disclosed normalization processes were enabled, however, there is no suggestion that the various normalization processes disclosed would be relevant to the hyperspectral imaging camera mentioned one time at paragraph [0178].

Because the asserted reference to Bambot is not enabling, at least with respect to the disclosed normalization processes, Bambot does not, and can not, anticipate any of claims 1-4 of the present application. Accordingly, withdrawal of the 102 rejection of claims 1-4 is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1-4 are further rejected under 35 U.S.C. § 103 as being unpatentable over Yang et al. in view of Bambot et al. Applicant submits, however, that Yang et al. does not compensate for the deficiencies described above with respect to Bambot et al.

Specifically, Yang et al. fails to teach or suggest normalization of fluorescence spectral signals collected from a hyperspectral data cube, as required by each of the rejected claims.

First, the *only* mention within Yang et al. of any normalization process is at column 10, lines 60-63 where it is disclosed, in regard to FIG. 7 that “[p]anel B shows this same contour in a fixed-scale mode, wherein each spectrum has been *normalized* to the minimum and maximum absorbance values for the entire dataset.” Similar to Bambot et al., however, Yang et al. does not provide an enabling disclosure with respect to the normalization process. No disclosure is provided in Yang as to how one would go about normalizing the mentioned spectrum with respect to minimum and maximum absorbance values. Accordingly, Yang et al. does not, and can not, teach or suggest the claimed normalization process of the instant application and even if combined with Bambot et al., as proposed, the result would not include an enabling disclosure of the claimed normalization process. For at least this reason the rejection of claims 1-4 under 35 U.S.C. § 103 should be withdrawn.

Additionally, normalization of the spectrum, as mentioned at column 10, lines 60-63 of Yang et al., is not related to hyperspectral data. Instead, in Yang et al. it is disclosed that the “contour plots”, as shown in FIG. 7, contain the data which is normalized (See col. 10, line 48 to col. 11, line 12). Accordingly, it is not disclosed in Yang et al. that fluorescence data from a hyperspectral data cube is normalized. Applicant recognizes that Yang et al. mentions “hyperspectral database management”

at col. 15, lines 41-48, however there is no disclosure that the hyperspectral data is normalized. The only disclosure in Yang et al. of normalization is in the context of the contour plots at column 10, lines 48-63 and have nothing to do with the hyperspectral database management mentioned at column 15, lines 41-48. For this additional reason the rejection of claims 1-4 under 35 U.S.C. § 103 should be withdrawn.

Lack of Prima Facie Case of Obviousness

Lastly, the grounds of rejection fail to set forth a *prima facie* case of obviousness. It is well settled that “[t]he PTO has the burden under section 103 to establish a prima facie case of obviousness, and it can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” *In re Joao*, 2003 U.S. App. LEXIS 22718, 1-2 (Fed. Cir. 2003). Here, there has been no *showing* of a motivation to combine, as required.

The grounds of rejection recognize that Yang et al. fails to teach application of its disclosure to cervical tissue. The grounds of rejection assert, however, that because Bambot allegedly discloses “a computer program for generating a two dimensional histological map of a cervix which includes color-coded regions representing specific tissue classifications of the cervix from a 3-dimensional hyperspectral data cube,” it follows that “a skilled artisan would have found it obvious to use the cervical tissue based teaching of Bambot et al. to modify the teaching by Yang et al. for the purpose of

generating a two-dimensional histological map of a cervix...". The grounds of rejection provide no rational basis for this conclusion, however.

Applicant recognizes that "[e]vidence of a suggestion, teaching, or motivation to combine prior art references may flow, *inter alia*, from the references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved." *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348-1349 (Fed. Cir. 2000). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, ***the showing of combinability, in whatever form, must nevertheless be "clear and particular."*** *Id.* Because the grounds of rejection fail to provide a clear and particular explanation as to why a skilled artisan would find it obvious to use the Yang et al. system and/or method for cervical tissue analysis, a *prima facie* case of obviousness has not been established and withdrawal of this rejection is, thus, kindly requested.

Patentability of New Claims

For additional claim coverage merited by the scope of the invention, Applicant has added new claims 5-11. Applicant submits that the prior art does not disclose, teach, or otherwise suggest the combination of features contained therein.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in

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issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 21-0380. Please also credit any overpayments to said Deposit Account.


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